Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of N-acetyl cysteine (NAC) and placebo in craving reduction in methamphetamine dependent subjects

Protocol summary

Summary

Nowadays methamphetamine is one of the most prevalent drugs of abuse in Iran. It can cause different medical such as cardiovascular side effects as well as psychiatric side effects like psychosis. Currently there is no approved drug for reducing craving for methamphetamine. N-acetyl cysteine is one of drugs that is suggested for this purpose according to previous trails on reduction of craving in methamphetamine and cocaine. This study uses a randomized, double-blind, placebo-controlled, cross over clinical trial design. Subjects will be treatment-seeking males and females who meet DSM-IV criteria for methamphetamine dependency, which will be selected from patients, who refer to Noor Hospital psychiatric emergency, psychiatric clinic or drug dependency treatment center. This will be done approximately from May, 2012 until May, 2013. After screening, eligible subjects were randomly assigned to NAC or placebo. For each group there will be a six weeks treatment program and then the placebo and NAC group will be exchanged. In NAC group drug will be started at 1200 mg/day and will be raised to 2400 mg/day after 2 weeks, and to 3600 mg/day after 4 weeks, and will be continued until week 6.The craving will be assessed with Cocaine Craving Questionnaire-Brief (CCQ-Brief) at screening and every 2 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205317841N2**
Registration date: **2012-07-13, 1391/04/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-07-13, 1391/04/23

Registrant information

Name

Mohammad Reza Sharbafchi

Name of organization / entity

Psychiatric group, Isfahan Univercity of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Behavioral Sciences Research Center

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of N-acetyl cysteine (NAC) and placebo in craving reduction in methamphetamine dependent subjects

Public title

Assessment of NAC efficacy for reducing of craving in patients with methamphetamine dependency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) men and women aged 18–65 years old; 2) informed acceptance to comply with study procedures. Exclusion criteria: 1) sever medical illness that would impair the ability to participate safely in the study; 2) a current neurological or axis I psychiatric disorders not due to substance abuse (e.g., schizophrenia, dementia) that would impair ability to participate safely in the study; 3) current pregnancy or nursing in women; 4) current serious suicidal intention or plan; 5) more than 3 times elevation of AST and ALT at screening; 6) past medical history of asthma or seizures; 7) Subjects who had recently used medications (<14 days) felt to be hazardous if taken with NAC (e.g. carbamazepine, nitroglycerin); and 8) subjects who met DSM-IV criteria for opiates dependence. Also in following conditions the patient will be out of study: 1) incidence of seizure or sever medical illness that would impair ability to participate safely in the study; 2) non compliance or not willing for continuing the study; 3) sever and unbearable drug side effect even after reducing the dose.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezarjarib Street

City

Isfahan

Postal code

Approval date

2012-05-30, 1391/03/10

Ethics committee reference number

8/3834/د

Health conditions studied

1

Description of health condition studied

Methamphetamine Dependency

ICD-10 code

F15.2

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use

Primary outcomes

1

Description

Methamphetamine Craving

Timepoint

At screening and every 2 weeks up to 6 weeks

Method of measurement

Cocaine Craving Questionnaire-Brief (CCQ-Brief)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: drug will be started at 1200 mg/day and will be raised to 2400 mg/day after 2 weeks, and to 3600 mg/day after 4 weeks, and will be continued until week 6.

Category

Treatment - Drugs

2

Description

Control: Placebo with numbers equal to main drug in 2 weeks intervals.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Drug Treatment Center, Emergency and Clinic of Noor Hospital

Full name of responsible person

Mohammad Reza Sharbafchi zade

Street address

Noor Hospital, Ostandari street

City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences, Behavioral Sciences Research Center
Full name of responsible person
Dr Abas Atari
Street address
Noor Hospital, Ostandari Street
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Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences, Behavioral Sciences Research Center
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty

Data Dictionary *empty*